

are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Fig. 1 is a diagrammatic view of a system for treating body sphincters and adjoining tissue regions, which embodies features of the invention;

Fig. 2 is a perspective view, with portions broken away, of a device usable in association with the system shown in Fig. 1 having an operative  
10 element for contacting tissue shown in a collapsed condition;

Fig. 3 is a perspective view, with portions broken away, of the device shown in Fig. 2, with the operative element shown in an expanded condition;

15 Fig. 4 is a perspective view, with portions broken away, of the device shown in Fig. 2, with the operative element shown in an expanded condition and the electrodes extended for use;

20 Fig. 5 is an enlarged view of the operative element shown in Fig. 4, with the electrodes extended for use;

Fig. 6 is a perspective view of a kit containing a device, such as shown in Figs. 2 to 5, and a usage key card;

25 Fig. 7 is an enlarged, mainly schematic view of the usage key card shown in Fig. 6, embodied as a floppy disk, and also showing the pre-formed files it contains;

30 Fig. 8 is a schematic view of a controller, which the system shown in Fig. 1 incorporates, showing the pre-programmed rules by which information contained on the usage key card shown in

Figs. 6 and 7 is read and processed; and

Fig. 9 is a schematic view of another processing device that reads information from the usage key card for further processing.

5 The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodi-  
10 ments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 shows one embodiment of a system 10,  
15 which monitors and controls the use of an operative element 12. The system 10 is well adapted for association with single use, catheter-based devices. Therefore, in the illustrated embodiment, the operative element 12 is part of a catheter-based  
20 treatment device 26. It should be appreciated, however, that the system 10 is also adaptable for use with devices and methods that are not necessarily catheter-based.

##### **A. The Treatment Device**

25 In the illustrated embodiment, the device 26 includes a handle 28 made, e.g., from molded plastic. The handle 28 is sized to be conveniently held by a physician, to introduce the catheter tube 30 into the targeted tissue region.

30 The handle 28 carries a flexible catheter tube 30. The catheter tube 30 can be constructed, for example, using standard flexible, medical grade

plastic materials. The catheter tube 30 has a distal end 34, which carries the operative element 12.

The operative element 12 can support, for example, a device for imaging body tissue, such as an endoscope, or an ultrasound transducer. The operative element 12 can also support a device to deliver a drug or therapeutic material to body tissue. The operative element 12 can also support a device for sensing a physiological characteristic in tissue, such as electrical activity, or for transmitting energy to stimulate or form lesions in tissue.

In the illustrated embodiment, the device 26, in use, is intended to treat dysfunction of sphincters and adjoining tissue regions in the upper gastrointestinal tract, e.g., in the lower esophageal sphincter and adjacent cardia of the stomach, as well as in the lower gastrointestinal tract, e.g., in the intestines, rectum and anal canal. Still, it should be appreciated that the system 10 can be used in association with other devices and methods used to treat other dysfunctions elsewhere in the body, which are not necessarily sphincter-related. For example, the various aspects of the invention have application in procedures requiring ablation of tissue throughout the body, or treatment of hemorrhoids, or restoring compliance to or otherwise tightening interior tissue or muscle regions.

In the illustrated embodiment, one function that the operative element 12 is to perform is to apply energy in a selective fashion to a targeted